OCT 2 9 2001

Oey, Jan

From: Kinser, Robin D.
Sent: Monday, October 29, 2001 4:38 PM
To: 'Jill Schultz'
Cc: Holt, Klaus von; Kuhl, Peter; Rustemeier, Klaus; Schepers, Georg; Stabbert, Regina; Tricker, Anthony; Roethig, Hans; Oey, Jan; Kinser, Robin D.
Subject: RE: MDA plasma validation data

Jill--The interim reports were supposed to include a sample chromatogram and calibration curve, and a short description of the method. I find none of these in what was submitted for MDA in plasma, nicotine glucuronide in urine and cotinine glucuronide in urine. I also seem not to have short term-stability studies for these analytes. We need the complete data before we can authorize analysis. Please review and let me know when to expect the additional information. Thanks.--Robin

-----Original Message-----
From: Jill Schultz [SMTP:jill.schultz@Covance.Com]
Sent: Friday, October 12, 2001 3:01 PM
To: Holt.Klausvon@pmintl.ch; kuhl.peter@pmintl.ch; rustemeier.Klaus@pmintl.ch; Schepers.Georg@pmintl.ch; Stabbert.Regina@pmintl.ch; tricker.anthony@pmintl.ch; Hans-Juergen.Roethig@pmusa.com; Jan.Oey@pmusa.com; robin.d.kinser@pmusa.com
Subject: Re: MDA plasma validation data

MDA plasma validation data are attached. Please not that additional stability data will be available next week. In addition, the attached data are not fully QC checked as Mark states below. If any of the values change following the final QC check, I will ask Mark to highlight the those values so that everyone is aware of the changes. I apologize for any inconvenience this may cause.

Regards,

Jill

>>> <mark.bentley@Covance.Com> 10/12/01 5:04:44 PM >>>

Hi Jill,

Please find attached preliminary validation data for the MDA plasma assay for PM review. Please note that we are currently awaiting extract stability data (running over the weekend) and stock solution stability data (covered by urine validation). Also, these data are not fully QC checked and may be subject to (very) minor alteration. I will forward 100% checked data, to include extract stability next week.

Cheers,

Mark....

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